

EXHIBIT 12

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.

15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:

Amy L. Larson, RPR

Job No. 113495

NACHTSHEIM
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NACHTSHEIM
 INDEX:
 EXAMINATION BY: PAGE
 Ms. Garcia.....8, 372
 Mr. Sacchet.....254
 EXHIBITS MARKED FOR IDENTIFICATION:
 Exhibit 1.....10
 Acknowledgment and Agreement to be Bound
 No Bates
 Exhibit 2.....10
 Notice of Videotaped Deposition of
 Christopher Nachtsheim
 No Bates
 Exhibit 3.....12
 Christopher Nachtsheim, Ph.D.,
 Curriculum Vitae
 No Bates
 Exhibit 4.....15
 Forced-Air warming and ultra-clean
 ventilation do not mix
 No Bates
 Exhibit 5.....15
 Patient Warming Excess Heat:
 The Effects on Orthopedic Operating
 Room Ventilation Performance
 No Bates
 Exhibit 6.....29
 Statistical Analysis for HPS Protocol 003
 Bates Albrecht_0016008 - Albrecht_0016012
 Exhibit 7.....34
 Research Agreement
 Bates Belani_000054 - Belani_000061
 Exhibit 8.....37
 Logistic Regression -
 Mark Albrecht - March 11, 2016
 Bates Albrecht_0002275 - Albrecht_0002278

NACHTSHEIM
 INDEX: (Cont'd.)
 EXHIBITS MARKED FOR IDENTIFICATION: PAGE
 Exhibit 9.....38
 11/1/2013 E-mail Chain
 Subject: Re: Analytically speaking
 Bates Albrecht_0000101 - Albrecht_0000102
 Exhibit 10.....53
 3/24/10 E-mail Chain
 Subject: First Publication I'd Like to
 Include you on
 Bates Nachtsheim_0000364 - Nachtsheim_0000382
 Exhibit 11.....58
 April 2010 E-mail Chain
 Subject: Testing
 Bates Nachtsheim_0001408 - Nachtsheim_0001410
 Exhibit 12.....62
 4/8/10 E-mail
 Subject: Update on testing
 Bates Nachtsheim_0001571
 Exhibit 13.....78
 4/9/10 E-mail
 Subject: Problem with laminar flow lab
 Bates Nachtsheim_0000832 - Nachtsheim_0000833
 Exhibit 14.....84
 April 2010 E-mail Chain
 Subject: Update
 Bates Nachtsheim_0001545 - Nachtsheim_0001547
 Exhibit 15.....95
 May 2010 E-mail Chain
 Subject: Abstract "crud and bug"
 !!!Important!!!
 Bates Nachtsheim_0000118 - Nachtsheim_0000120
 Exhibit 16.....100
 5/29/10 E-mail
 Subject: Both abstracts,
 Statistical files and data files
 Bates Nachtsheim_0000191 - Nachtsheim_0000192,
 Nachtsheim_0000211 - Nachtsheim_0000223

NACHTSHEIM
 INDEX:
 EXHIBITS MARKED FOR IDENTIFICATION: PAGE
 Exhibit 17.....114
 July 2010 E-mail Chain
 Subject: Manuscript drafts for meeting
 Bates Nachtsheim_0000548 - Nachtsheim_0000549,
 Nachtsheim_0000556 - Nachtsheim_0000576,
 Nachtsheim_0000600 - Nachtsheim_0000608,
 Nachtsheim_0000577 - Nachtsheim_0000599,
 Nachtsheim_0000613 - Nachtsheim_0000615
 Exhibit 18.....146
 7/8/10 E-mail
 Subject: Arizant FDA Warning Ltr
 Bates Nachtsheim_00000385
 Exhibit 19.....188
 1/4/11 E-mail Chain
 Subject: Article I was talking about
 Bates Nachtsheim_0000177 - Nachtsheim_0000179
 Exhibit 20.....192
 December 2010/January 2011 E-mail Chain
 Subject: Rough Copy
 Bates Nachtsheim_0001110 - Nachtsheim_0001115,
 Nachtsheim_000127 - Nachtsheim_000130,
 Nachtsheim_0001199 - Nachtsheim_0001201,
 Nachtsheim_0001206
 Exhibit 21.....195
 Forced Air Warming versus Conductive
 Fabric Warming - An Evaluation of
 Laminar Operating Room Ventilation Disruption
 Bates Nachtsheim_0001206 - Nachtsheim_0001229
 Exhibit 22.....205
 Implementing Effective SSI Surveillance
 No Bates
 Exhibit 23.....226
 1/25/11 E-mail Chain
 Subject: Minor Changes and a Query
 Bates Nachtsheim_0000750 - Nachtsheim_0000751,
 Nachtsheim_0000727 - Nachtsheim_0000749

Page 6

1	NACHTSHEIM	
2	INDEX: (Cont'd.)	
3	EXHIBITS MARKED FOR IDENTIFICATION: PAGE	
4	Exhibit 24.....231	
5	January 2011 E-mail Chain	
6	Subject: Papers you are involved in	
7	Bates Nachtsheim_0000819 - Nachtsheim_0000821	
8	Exhibit 25.....277	
9	April 2015 E-mail Chain	
10	Subject: Statistical Practitioners Forum:	
11	Advanced DOE Class	
12	Bates 3MBH01293497 - 3MBH01293499	
13	Exhibit 26.....322	
14	Doctor Says a Device He Invented	
15	Poses Risks	
16	No Bates	
17	Exhibit 27.....333	
18	Table	
19	Bates Albrecht_0002298	
20	Exhibit 28.....341	
21	Would Complications Following Rivaroxaban	
22	Administration - A Multi-Centre Comparison	
23	with Low Molecular Weight Heparin for	
24	Thromboprophylaxis in Lower Limb	
25	Arthroplasty	
	Bates Nachtsheim_0000451 - Nachtsheim_0000466	
	Exhibit 29.....369	
	Forced-Air Warming Does Not Worsen Air	
	Quality in Laminar Flow Operating Rooms	
	Bates 3MBH00985628 - 3MBH00985633	
	Exhibit 30.....377	
	Curriculum Vitae	

Page 7

NACHTSHEIM

THE VIDEOTAPED DEPOSITION OF CHRISTOPHER NACHTSHEIM, taken on this 29th day of November, 2016, at the Law Offices of Faegre Baker Daniels, LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota, commencing at approximately 9:11 a.m.

P R O C E E D I N G S

THE VIDEOGRAPHER: This is the Start of tape labeled number 1 of the videotaped deposition of Christopher Nachtsheim in the matter of In Re: Bair Hugger Forced Air Warming Products Liability Litigation in the U.S. District Court for the District of Minnesota, Case Number 15-2666 (JNE/FLM).

This deposition is being held at the Faegre Baker law firm in Minneapolis, Minnesota, on November 29th, 2016. We are going on the record at 9:11 a.m. My name is Kraig Hildahl, I'm the legal video specialist from TSG Reporting. The court reporter is Amy Larson also in association with

Page 8

NACHTSHEIM

TSG Reporting.

Will counsel please introduce themselves for the record.

MS. GARCIA: Christin Garcia, counsel for defendants 3M and Arizant.

MS. LEWIS: Deborah Lewis also counsel for defendants 3M and Arizant.

MR. SACCHET: Michael Sacchet for plaintiffs.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness and then we can proceed.

CHRISTOPHER NACHTSHEIM, a witness in the above-entitled action, after having been first duly sworn, was deposed and says as follows:

EXAMINATION

BY MS. GARCIA:

Q. Hello, Professor Nachtsheim.

A. Hello.

Q. Thank you for coming here today. Could you start by, for the record, just providing your

Page 9

NACHTSHEIM

full name and spell your last name and let us know your address.

A. Christopher John Nachtsheim. And it's N as in north, A-C-H-T, S as in Sam, H-E-I-M. Address is 1789 Summit Avenue, St. Paul, Minnesota 55105.

Q. Thank you. Have you ever been deposed before?

A. Yes.

Q. Okay. The one rule of deposition I just want to reinforce today is if you have any difficulty understanding -- well, if you don't understand my question, if you would like me to clarify something, will you please let me know that?

A. Uh-huh. Yes.

Q. Yes?

A. Yes.

Q. There's rule number 2.

A. That's rule number 2, I knew that.

Q. You will need to say things out loud so that we can get an accurate transcription of the record in writing where your head movements can't be taken down, and then we will try not

<p style="text-align: right;">Page 322</p> <p>1 NACHTSHEIM</p> <p>2 MR. SACCHET: Sure.</p> <p>3 THE WITNESS: Yes.</p> <p>4 (Whereupon, Exhibit 26 was</p> <p>5 marked for identification.)</p> <p>6 MR. SACCHET: I believe it was</p> <p>7 marked, was it?</p> <p>8 THE WITNESS: Yeah, this is</p> <p>9 Exhibit 26.</p> <p>10 BY MR. SACCHET:</p> <p>11 Q. So does the website address at the bottom</p> <p>12 left-hand corner of Exhibit 26 --</p> <p>13 A. Oh, does it match, I see what you're saying.</p> <p>14 Q. -- match the --</p> <p>15 A. Yes, it does. It does.</p> <p>16 Q. If you could take a moment to just scan the</p> <p>17 three odd pages of the article.</p> <p>18 A. (Reviews document.)</p> <p>19 MS. GARCIA: Is there a question?</p> <p>20 MR. SACCHET: There's not one</p> <p>21 pending.</p> <p>22 MS. GARCIA: Okay. Thank you.</p> <p>23 THE WITNESS: (Reviews document.)</p> <p>24 Okay.</p> <p>25 BY MR. SACCHET:</p>	<p style="text-align: right;">Page 323</p> <p>1 NACHTSHEIM</p> <p>2 Q. Just a few quick questions about the article.</p> <p>3 Did you find any reference to the</p> <p>4 McGovern study or the McGovern data in the</p> <p>5 article?</p> <p>6 A. I did not.</p> <p>7 Q. This study was -- or this article from the</p> <p>8 New York Times was in fact published</p> <p>9 approximately 11 months before the McGovern</p> <p>10 article was published, wasn't it?</p> <p>11 A. Yes, it was.</p> <p>12 Q. The only data mentioned in the article are</p> <p>13 those presented to the ECRI Institute that</p> <p>14 you can find at the top of the last full text</p> <p>15 page, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And at the bottom of the article is</p> <p>18 presumably what you and Mr. Albrecht were</p> <p>19 referring to in your correspondence marked in</p> <p>20 Exhibit 19 in which you say something to the</p> <p>21 effect of, "His statement is hard to argue</p> <p>22 with," correct?</p> <p>23 MS. GARCIA: Object to the form of</p> <p>24 the question.</p> <p>25 THE WITNESS: I just wanted to</p>
<p style="text-align: right;">Page 324</p> <p>1 NACHTSHEIM</p> <p>2 review where that shows up. Is that --</p> <p>3 MR. SACCHET: That's --</p> <p>4 THE WITNESS: That's what --</p> <p>5 MR. SACCHET: Exhibit --</p> <p>6 THE WITNESS: Oh, yes, "Hard to</p> <p>7 disagree with the last quote" --</p> <p>8 MR. SACCHET: The last quote.</p> <p>9 THE WITNESS: -- "where the guy</p> <p>10 said the data are compelling, but they don't</p> <p>11 prove a link to infections in practice and a</p> <p>12 clinical trial would be needed to do that?</p> <p>13 MR. SACCHET: Yup.</p> <p>14 BY MR. SACCHET:</p> <p>15 Q. And the last quote also says that, "Proving</p> <p>16 such a link might be impossible, because it</p> <p>17 would require mounting a huge clinical</p> <p>18 study," correct?</p> <p>19 A. Correct.</p> <p>20 Q. In the absence of a clinical study, is the</p> <p>21 next best evidence observational data?</p> <p>22 MS. GARCIA: Object to the form of</p> <p>23 the question.</p> <p>24 THE WITNESS: Yes. In the absence</p> <p>25 of a -- of an experimental or a clinical</p>	<p style="text-align: right;">Page 325</p> <p>1 NACHTSHEIM</p> <p>2 study, it's the -- the only evidence you</p> <p>3 would have would be observational data.</p> <p>4 BY MR. SACCHET:</p> <p>5 Q. And you agreed with the statement made by</p> <p>6 Dr. Jeffrey Gumprecht that it would be</p> <p>7 impossible to mount a huge clinical study,</p> <p>8 correct?</p> <p>9 MS. GARCIA: Object to the form of</p> <p>10 the question.</p> <p>11 THE WITNESS: I -- I really -- I</p> <p>12 really don't know for sure that it would be</p> <p>13 impossible. I don't know what -- first of</p> <p>14 all, I think it's possible. I don't know</p> <p>15 what it would cost. I don't know -- I'd have</p> <p>16 to think through how that kind of study would</p> <p>17 be designed and -- and -- and the logistical</p> <p>18 problems that might present themselves. I</p> <p>19 don't see any impossibility.</p> <p>20 MR. SACCHET: Okay.</p> <p>21 BY MR. SACCHET:</p> <p>22 Q. Assuming a randomized control trial could not</p> <p>23 be conducted, observational data would be the</p> <p>24 next best alternative?</p> <p>25 MS. GARCIA: Object to the form of</p>

Page 326

NACHTSHEIM

the question.

THE WITNESS: That would be the next best alternative.

BY MR. SACCHET:

Q. Why is that?

A. Here what we're doing with the -- with the randomized -- with a clinical trial is that we're going to actually put both -- both types of blankets in practice and we can look at -- look directly at infection rates that result from the two different conditions, and that's the -- that's the clinical study. If you're looking at -- if you want to know about infections, I think you're limited to looking at observational studies such as -- such as the one that we report on.

We did -- we did experimental studies on bubbles, but we can't do experimental studies on infections without -- without resorting to a clinical trial of some kind.

So I think that, yeah, I think you probably -- if you want to look at infections, I think you're -- I think you're

Page 327

NACHTSHEIM

probably limited to observational data.

Q. Isn't it true that a well-designed observational study can render results extremely similar to a properly conducted randomized trial --

MS. GARCIA: Object --

BY MR. SACCHET:

Q. -- on the same subject matter?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I think that can happen, but I don't believe that the level of proof reaches the same -- I don't think that the proof reaches the same level of rigor. There's just always that chance in observational studies that -- I mean, I think there's a greater chance that something -- a confounding factor might be present, something you just hadn't thought of.

BY MR. SACCHET:

Q. But it is possible that if statistical significance is found based on observational data, that that significance may be replicated in a randomized control trial?

Page 328

NACHTSHEIM

A. Yes.

Q. So the observational data that is presented in the McGovern study is certainly valuable, is it not?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I think it's valuable.

BY MR. SACCHET:

Q. That's why you published the observational data, correct?

A. Yes.

Q. You were previously asked about potentially confounding factors with respect to the observational data that was presented in the McGovern study, correct?

A. Correct.

Q. And some of those potentially confounding factors dealt with infection control measures, correct?

A. Correct.

Q. If we could turn to page 1540 of Exhibit 4, the McGovern study.

A. (Complies.)

Page 329

NACHTSHEIM

Q. I want to make sure that we are on the same page with respect to the change that occurred as to the antibiotic regime. Would you agree that an antibiotic called Gentamycin was applied during the forced-air warming period from July 1st, 2008, to the end of February 2009? It's about halfway down the paragraph.

A. I see it. From July 2008 to February 2009 a single dose of Gentamicin 4.5 was given at -- at induction.

Q. Whereas, a combination of Gentamycin and Teicoplanin -- and I'd be surprised if any of us know how to pronounce it, but that's how I'm going to say it -- was applied during the end of the forced-air warming period and throughout the entire conductive fabric warming period, which would namely be March 1st, 2009, until January 2011, correct?

MS. GARCIA: Can you please point to where you're reading from?

MR. SACCHET: So I am interpreting what's said in this paragraph and based on what's presented in Figure 7 so --

MS. GARCIA: Okay. Then I'll

Page 330

NACHTSHEIM

object to the form of the question.

THE WITNESS: I -- I read this --

MR. SACCHET: I can walk through it slower.

THE WITNESS: Well, I read this to say that in March 2009 there was a change to the combination of the two drugs you've pronounced, and I don't believe there were any changes until the end of the study.

MR. SACCHET: Okay.

BY MR. SACCHET:

Q. So -- so we're clear, there was a period in which Gentamycin was applied to some forced-air warming patients, and then the antibiotic changed to a combination of Gentamycin and Teicoplanin that applied to some forced-air warming patients and all of the conductive fabric warming patients, correct?

A. Correct.

Q. Assuming the change in antibiotic did not affect infection rates between warming devices, would you still consider the antibiotic a confounding variable?

Page 331

NACHTSHEIM

MS. GARCIA: Object to the form of the question.

THE WITNESS: I'm going to assume that it has -- the change had no effect?

BY MR. SACCHET:

Q. Yeah, assume that the antibiotic had no effect on the infection rate. Would it still be a confounding variable?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I don't think it would be -- I don't think it would be considered a confounding variable. I'm trying to think of how else it might have an impact, if it's not having an effect. I guess it -- no, I don't think it would be, yeah.

BY MR. SACCHET:

Q. One way that we could control for the -- let me strike that.

In order to determine whether the antibiotic had an effect on infection rates, we could control for the warming device --

A. Yes.

Page 332

NACHTSHEIM

Q. -- and evaluate whether infection rates between the changed antibiotic stayed the same or went up or down --

A. Correct.

Q. -- with that control device, correct?

A. (Nods head.)

MS. GARCIA: I'm going to object to the form of the question.

BY MR. SACCHET:

Q. Did you understand it?

A. Yes.

Q. If infection rates between the two groups were similar, that would tend to show that the antibiotic was not a confounding factor?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. Assume that Mr. Albrecht, who you previously mentioned was an expert in statistics and you had full confidence in his ability to analyze data presented in this article, informed you that he found a 2.8 percent infection rate in those who received Gentamycin, a single drug,

Page 333

NACHTSHEIM

but 3.1 percent of patients who received the combination of antibiotics, but also forced-air warming patients, with a nearly identical infection rate, would you determine that the antibiotic was a confounding factor?

MS. GARCIA: Object to the form of the question.

THE WITNESS: That would be strong evidence that it was not a confounding factor.

MR. SACCHET: Let's mark this. (Whereupon, Exhibit 27 was marked for identification.)

BY MR. SACCHET:

Q. So just to be clear, if we look at this table that's presented here, we can see in the first line it presents antibiotic protocol 1 versus 2 for FAW, does it not?

A. It does.

Q. Assume that protocol 1 is the singular antibiotic, i.e. Gentamycin, and that protocol 2 is the combination of Gentamycin and Teicoplanin.

A. Uh-huh. Yes.

Page 334

NACHTSHEIM

Q. In this particular analysis, forced-air warming is held constant, correct?

A. Correct.

Q. And for forced air, protocol 1, the percent of patients developing infection was 2.8?

A. Correct.

Q. And for forced air, protocol 2, involving patients who received both Gentamycin and Teicoplanin, the infection rate was 3.1, correct?

A. Correct.

Q. And the p-value was 0.839, correct?

A. That's what's reported here.

Q. That's what's reported here. We could conclude, based on this data set of these numbers, that when the patient-warming device is held constant, that the change in antibiotic had no effect on infection rates, correct?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Assuming there's sufficient power in those sample sizes, although they look fairly large to me, yes.

Page 335

NACHTSHEIM

BY MR. SACCHET:

Q. The patient population for forced-air protocol 1 was 389 patients, correct?

A. Correct.

Q. And the patient population for those receiving the combination was 678, correct?

A. Correct.

Q. Those are fairly large patient populations, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. Another way to determine whether the antibiotic was a confounding variable would be to control the antibiotic, but evaluate different infection rates between different forced-air -- or different warming devices, correct?

A. Yes.

MS. GARCIA: Object to the form of that question also.

BY MR. SACCHET:

Q. And if the infection rates were still higher

Page 336

NACHTSHEIM

among those who received forced-air warming compared to those who received conductive fabric warming, that would tend to show the antibiotic did not substantially affect infection rates, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. And if that's true, the change in antibiotic would also not be a confounding factor, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. If I could --

MR. SACCHET: Could I ask your basis for the objection?

MS. GARCIA: I'm sorry?

MR. SACCHET: Could I ask your basis for the objection on form?

MS. GARCIA: Yes. You keep using the word, "determine," and you keep using the

Page 337

NACHTSHEIM

word, "show," and you keep using the word, "establish," and I'm objecting to the form of the question based on those terms.

MR. SACCHET: That's not going to pass muster in the court.

BY MR. SACCHET:

Q. As to the hypothetical I just presented, if you could turn your attention to the second line of the table.

MS. GARCIA: I'm sorry, to just be complete with my form objection, it's also an incomplete hypothetical.

MR. SACCHET: Fair enough.

BY MR. SACCHET:

Q. Antibiotic protocol 2 involved a combination have Gentamycin and Teicoplanin, correct?

MS. GARCIA: Object to

foundation --

BY MR. SACCHET:

Q. -- for the sake of --

A. Yes.

MS. GARCIA: Excuse me. Object to foundation for that.

BY MR. SACCHET:

NACHTSHEIM

Q. And the data here shows that 3.1 percent of patients who received forced-air warming in the combination antibiotic developed joint infections, correct?

A. Correct.

Q. Whereas, .9 percent of patients who received conductive fabric warming and the combination of antibiotics developed joint infections, correct?

A. Correct.

Q. By holding the antibiotic constant and discontinuing the use of forced-air warming, that resulted in a 71 percent decrease in joint infections, did it not?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Yes, it did.

BY MR. SACCHET:

Q. That essentially matches the 73 percent decrease in infections that was noted in the McGovern article itself, does it not?

A. Correct.

MS. GARCIA: Object to the form of the question.

NACHTSHEIM

BY MR. SACCHET:

Q. And based on the p-value of .0008, which is far less than .05, you would determine that difference to be statistically significant, would you not?

A. I would.

Q. So whether we control for the device or control for the antibiotic, based on this data set in Exhibit 27, would you determine that the antibiotic was not a confounding factor?

MS. GARCIA: Object to the form of the question, it's a lack of foundation, it's an incomplete hypothetical.

THE WITNESS: This data certainly supports that hypothesis.

BY MR. SACCHET:

Q. And if it were not a confounding factor, would there be any reason to deselect patients from the population of 1,437 accounted for in the McGovern study in order to exclude those who received a single antibiotic?

A. No.

NACHTSHEIM

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. And if we were to do that and reduce the population, let's say, from the 1,473, or 37, I've forgotten which number it is, down to a number of let's say 500 patients, there could be concern about the powering of that population?

A. There could. There could be.

Q. Another confounding factor that was discussed this afternoon was a change in the thromboprophylaxis protocol, correct?

A. Yes. Can -- can you just remind me where that --

Q. Yeah, if we could turn to page 1540.

A. (Complies.)

Q. If you look at the bottom of the first full paragraph in the left-hand column, it states the thromboprophylaxis regimen from July 2008 to the end of July 2009 was Tinzaparin.

A. Uh-huh.

Q. Then it says from August 2009 to February

NACHTSHEIM

2010, Rivaroxaban, which I'll represent is otherwise known as Xarelto, was provided from day one, but in February 2010 to the end of this study, patients were reverted to Tinzaparin, correct?

A. Yes.

Q. Assuming the change in the prophylaxis did not affect infection rates during the time of this study, i.e., Exhibit 4, would you still consider it a confounding variable?

A. No.

MS. GARCIA: Object to the form of the question.

(Whereupon, Exhibit 28 was marked for identification.)

MS. GARCIA: What number are we on?

MR. SACCHET: Twenty-eight, I believe.

THE COURT REPORTER: Correct.

MS. GARCIA: Thank you.

BY MR. SACCHET:

Q. Have you seen this document before, Professor?

NACHTSHEIM

A. No, I have not.

Q. Was this document produced with the set of documents that you provided to 3M in response to the subpoena?

A. No.

Q. Does the bottom right-hand label of this document bear a Bates number of Nachtsheim --

A. It does.

Q. -- space 0000451?

A. It must have been attached to one of my e-mails. I -- I -- I don't remember seeing the document.

Q. Since you don't remember receiving or reading the document, let's go through it.

A. Okay.

Q. If you'd turn to the second page of text that bears the heading, "Introduction"; do you see that?

A. I do.

Q. Do you see the last paragraph at the bottom of that page?

A. "This multicenter study"?

Q. Correct. I'll read it out loud and you just confirm that we're on the same page. "This

NACHTSHEIM

multicenter study based on prospectively collected national data aims to evaluate the surgically relevant complications of using either Rivaroxaban, or LMWH," which I'll represent means low molecular weight heparins, "as thromboprophylaxis, including wound complications, readmission and return to theater for deep infection, in addition to the incidents of major bleeds and EVT," correct?

A. Correct.

Q. Based on that statement, do you agree that at least two or three outcomes were measured, one being wound complications, another being return to theater for deep infection, and another being major bleeds?

A. I agree.

MS. GARCIA: I object to lack of foundation.

BY MR. SACCHET:

Q. If you could turn to the next page under, "Methods," in the third paragraph it states, "The primary outcome measure was wound complications," parens, "Including hematoma,

NACHTSHEIM

superficial wound infection and deep infection requiring return to theater, RTT, within 30 days of procedure"; do you see that?

A. I do.

Q. And you see the designation that RTT involves a deep infection requiring a return to theater, correct?

A. Correct.

Q. Which is one of the independent variables that was mentioned in the prior paragraph that we read, correct?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Correct. I think dependent variables.

MR. SACCHET: Okay. Noted.

BY MR. SACCHET:

Q. If we can now turn to the next page under, "Results," do you see that heading?

A. Yes, 456.

Q. It says, "During the study period, 2,762 patients received Rivaroxaban, and 10,361 received LMWH. Patient demographics are

NACHTSHEIM

shown in table 1. There were significantly fewer wound complications in the LMWH group," parens, "2.81 percent versus 2.85 percent, OR equals .72, 95 percent confidence intervals between 0.58 to 0.90 with a p-value of .005. However, rates of RTT for infected wound washout were not significantly different." Do you see that?

A. I do.

Q. Assuming the truth of this study in what we just read, would you agree that Rivaroxaban, otherwise known as Xarelto, increased wound complications compared to low weight molecular heparins like Tinzaparin?

MS. GARCIA: Object to the form of the question, to an incomplete hypothetical and to a lack of foundation for this witness to opine about the meaning of this article.

THE WITNESS: It says there were significantly fewer wound complications in the LMH -- LMWH group. Is that what you're referring to?

BY MR. SACCHET:

Q. That's what I'm referring to. And the

<p style="text-align: right;">Page 346</p> <p>1 NACHTSHEIM</p> <p>2 p-value was a statistically significant</p> <p>3 value, correct?</p> <p>4 A. Yes, correct.</p> <p>5 Q. So there were fewer wound complications as a</p> <p>6 result of the use of a low weight molecular</p> <p>7 heparin --</p> <p>8 A. Correct.</p> <p>9 Q. -- compared to Rivaroxaban, correct?</p> <p>10 A. Yeah, correct.</p> <p>11 MS. GARCIA: Object to the form of</p> <p>12 the question.</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. However, the study notes that rates for RTT,</p> <p>15 which we established to be a return to</p> <p>16 theater for --</p> <p>17 A. Uh-huh.</p> <p>18 Q. -- infections, were not significantly</p> <p>19 different; do you see that?</p> <p>20 A. Correct. Yes, I do.</p> <p>21 Q. Assuming the truth -- well, let me back up.</p> <p>22 Would you also agree that the</p> <p>23 McGovern study, Exhibit --</p> <p>24 MS. GARCIA: Four.</p> <p>25 BY MR. SACCHET:</p>	<p style="text-align: right;">Page 347</p> <p>1 NACHTSHEIM</p> <p>2 Q. -- 4, evaluated joint infections?</p> <p>3 A. Yes.</p> <p>4 Q. It did not evaluate wound complications, did</p> <p>5 it?</p> <p>6 A. Correct, it did not.</p> <p>7 Q. Assuming the truth of this study, would you</p> <p>8 ultimately agree that the change in protocol</p> <p>9 from Tinzaparin, which is an LMWH, to</p> <p>10 Xarelto, otherwise known as Rivaroxaban, and</p> <p>11 then back to Tinzaparin, did not</p> <p>12 significantly affect the infection rate?</p> <p>13 MS. GARCIA: Object to the form of</p> <p>14 the question, to lack of foundation, and it's</p> <p>15 an incomplete hypothetical.</p> <p>16 THE WITNESS: Assuming the study</p> <p>17 was carefully done and generalizable, yes.</p> <p>18 BY MR. SACCHET:</p> <p>19 Q. And assuming the study was well done and</p> <p>20 generalizable, would you agree that the</p> <p>21 change in thromboprophylaxis noted in the</p> <p>22 McGovern study, Exhibit 4, did not confound</p> <p>23 the infection rates?</p> <p>24 MS. GARCIA: Object to the form of</p> <p>25 the question.</p>
<p style="text-align: right;">Page 348</p> <p>1 NACHTSHEIM</p> <p>2 THE WITNESS: Assuming -- yes.</p> <p>3 BY MR. SACCHET:</p> <p>4 Q. And would you also conclude that, assuming</p> <p>5 the truth of this study, it would be improper</p> <p>6 to deselect all of the patients who received</p> <p>7 Xarelto, otherwise known as Rivaroxaban, from</p> <p>8 the patient population if the</p> <p>9 thromboprophylaxis was not a confounding</p> <p>10 variable?</p> <p>11 MS. GARCIA: Object to the form of</p> <p>12 the question.</p> <p>13 THE WITNESS: It doesn't seem</p> <p>14 justified in -- on the basis of these</p> <p>15 results.</p> <p>16 BY MR. SACCHET:</p> <p>17 Q. And, in fact, when the coauthors of the</p> <p>18 McGovern study were in the process of</p> <p>19 publication, are you aware that at numerous</p> <p>20 times they sought to collect additional data</p> <p>21 in support of the study?</p> <p>22 A. I was not aware of that. I knew that -- I</p> <p>23 knew that they sought to run this study out</p> <p>24 in time.</p> <p>25 Q. Are you aware that when Mr. Albrecht and</p>	<p style="text-align: right;">Page 349</p> <p>1 NACHTSHEIM</p> <p>2 Dr. Reed collected additional data that went</p> <p>3 beyond January 2011 in the conductive fabric</p> <p>4 warming population, that the data still</p> <p>5 showed a significant decrease in infections</p> <p>6 when conductive fabric warming was used?</p> <p>7 A. I'm aware of that.</p> <p>8 Q. Assuming that --</p> <p>9 MS. GARCIA: Can we take a break</p> <p>10 shortly?</p> <p>11 MR. SACCHET: Yeah, give me two</p> <p>12 minutes.</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. Assuming that neither the antibiotic nor the</p> <p>15 thromboprophylaxis protocol required control</p> <p>16 because they were not confounding factors as</p> <p>17 we discussed, you would be confident in the</p> <p>18 results of the observational study presented</p> <p>19 in the McGovern data?</p> <p>20 MS. GARCIA: Object to the form of</p> <p>21 the question.</p> <p>22 THE WITNESS: I'm confident that</p> <p>23 those weren't confounding factors, that those</p> <p>24 studies are well done. It doesn't rule out</p> <p>25 the potential for other confounding factors.</p>

Page 350

NACHTSHEIM

MR. SACCHET: Fair enough.

BY MR. SACCHET:

Q. And you continue to stand by the results of the observational studies --

A. Yes.

Q. -- in the McGovern publication?

A. I do.

MR. SACCHET: Let's take a break.

THE VIDEOGRAPHER: We're going off the record at 5:07 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: This is video number 6 in the deposition of Christopher Nachtsheim. Today is November 29th, 2016. We're going back on the record at 5:18 p.m.

BY MR. SACCHET:

Q. Professor Nachtsheim, if we could turn to Exhibit 5, which is the Belani study.

A. I have it.

Q. Great. And as to this study, your role was to exclusively review the statistical portion of this study, correct?

A. Correct.

Page 352

NACHTSHEIM

MS. GARCIA: Object to the form of the question, misstates the record and lack of foundation.

THE WITNESS: Correct.

BY MR. SACCHET:

Q. If we could turn to the third page of the study.

A. (Complies.) 408?

Q. Yes. Do you see the header entitled, "Statistical Analysis"?

A. I do.

Q. And it reads, "A Poisson regression model for overdispersed data was fit having the sum of bubble counts for each experimental run," paren, "ten pictures," end parens, "as the response, and the factors identified in the experimental design as predictors plus an interaction term." Do you see that?

A. I do, yes.

Q. Did you determine that a Poisson regression was the most appropriate statistical model to employ because you were dealing with counts data -- or data counts?

A. Yes.

Page 351

NACHTSHEIM

Q. You had no involvement in the setup of the experiment?

A. I did not.

Q. You had no role in the execution of the physical experiment?

A. I did not.

Q. You had seen, whether by video or in person, disruption of laminar flow caused by the Bair Hugger before, correct?

A. I had, yes.

MS. GARCIA: I'm sorry, can I hear that question again? I was thinking and I did not hear the question.

MR. SACCHET: Can you -- do you mind repeating it.

(Whereupon, the last question was read by the court reporter.)

MS. GARCIA: Object to the form of the question, asked and answered.

BY MR. SACCHET:

Q. So you were familiar with the possibility, based on your personal experience, that the Bair Hugger could disrupt laminar airflow, correct?

Page 353

NACHTSHEIM

MS. GARCIA: Object to the form of the question, previously asked and answered.

BY MR. SACCHET:

Q. And that Poisson regression was a better model to use than, let's say, an ANOVA model?

MS. GARCIA: Object to the form of the question, previously asked and answered.

THE WITNESS: Yes.

BY MR. SACCHET:

Q. And if we could just turn our attention one paragraph above that, it says, "For the experimental design, a replicated and equals to 2 by 3 full factorial design was used to assess changes in bubble counts over the surgical site," correct?

A. Correct.

Q. And what were the factors?

A. So the first factor is the anesthesia screen, low grade/high grade, those are the two levels, and then there were three patient-warming devices, conductive fabric, forced-air or no warming device, and that would -- that was considered a control.

Q. Does Figure 3, directly above that paragraph,